

Notice of Allowability

Application No.

10/091,447

Examiner

Anthony J. Paviglianiti

Applicant(s)

MATSUMOTO ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's reply to restriction requirement dated March 10, 2005.
2. ☒ The allowed claim(s) is/are 1 - 10, as amended by examiner's amendment.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 06/10/02; 07/17/03 & 6/14/04 AJP
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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DETAILED ACTION

Applicant's response to the restriction requirement dated February 18, 2005, has been entered; accordingly, **Claims 5 – 10** were withdrawn from further consideration as being drawn to a non-elected invention pursuant to 37 C.F.R. §1.142(b). However, after examination of the application and determination that certain claimed chemical compounds of the invention were free of the prior art and allowable, the requirement for restriction was expressly withdrawn by the examiner and **Claims 5 – 10** were rejoined for examination on the merits. Therefore, **Claims 1 – 10** are currently pending in the application and were examined on the merits for patentability. An Examiner's Amendment follows the analysis below.

Priority

Acknowledgement is made of applicant's claim for foreign priority under 35 U.S.C. §119 (a) – (d), by Japanese Patent Application No. JP 2001-065,347, with filing date March 8, 2001.

Information Disclosure Statement

The Information Disclosure Statements filed on June 10, 2002, July 17, 2003, and June 14, 2004, are in compliance with 37 C.F.R. §1.97, and were considered by the examiner.

Election/Restriction and Rejoinder of withdrawn claims

Applicant's election, with traverse, of the invention of **Group I (Claims 1 – 4)**, in his Response and Remarks dated March 10, 2005, is respectfully acknowledged. The restriction requirement by examiner Sam P. Siefke, mailed February 18, 2005, required restriction between product and process claims. After examination of the elected invention of **Claims 1 – 4**, it was determined that certain claimed compounds were free of the prior art and directed to an

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allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims which were directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. **Claims 5 – 10 are hereby rejoined and fully examined for patentability under 37 C.F.R. §1.104.**

Since all claims previously withdrawn from consideration under 37 C.F.R. §1.142 have been rejoined, the restriction requirement made in the Office action mailed on February 18, 2005, is hereby withdrawn.

Response to Arguments

Applicant's arguments for the basis to rejoin the non-elected claims (**Claims 5 – 10**) for examination are made moot by the **rejoinder of all claims for examination** (see above), and therefore will not be addressed.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Agreement for the following examiner's amendment was reached in a telephone interview with Roland Martin, Esq., on June 7, 2005, and final authorization given by Mr. Martin on June 9, 2005.

The application has been amended as follows:

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In the claims:

In **Claim 1**, page 46, line 3, insert ---wherein Ar is--- before the terms “a group of the formula.”

In **Claim 8**, page 48, lines 5 and 6, delete “a substance to be detected” after the terms “comprises measuring,” and insert ---hormones, alpha-fetoprotein (AFP), carcinoembryonic antigen (CEA), viral antigens and antibodies, and nucleic acids---.

In **Claim 9**, page 48, lines 8 and 9, delete “letting a compound having a 1,2-dioxetane structure emit light” after the terms “which comprises,” and insert ---the emission of light from the 1,2-dioxetane derivative as defined in claim 1--- .

In the Abstract:

At **Abstract**, page 49, lines 4 – 10, delete “each of R^1 and R^2 which are independent of each other, is a hydrogen atom, an alkyl group or an aryl group, or R^1 and R^2 may together form a cyclic or polycyclic organic ring group spiro-bonded to the dioxetane ring, R^3 is an alkyl group or an aryl group, or R^3 and R^1 or R^2 may together form a condensed ring containing the dioxetane ring and a hetero atom, and”.

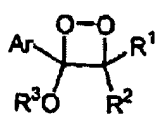
At **Abstract**, page 49, line 13 through page 50, line 3, delete “wherein R^4 is a hydroxyl group, an alkoxyl group, an aralkyloxy group, a group of $OSi(R^5R^6R^7)$ (wherein each of R^5 , R^6 and R^7 which are independent of one another, is an alkyl group or an aryl group), a phosphate group or a group of $-S(C=O)R^8$ (wherein R^8 is an alkyl group or an aryl group), each of R^9 and R^{10} which are independent of each other, is a hydrogen atom, an alkyl group, an aryl group or a halogen atom, X is a halogen atom, and V is an oxygen atom or a sulfur atom,”.

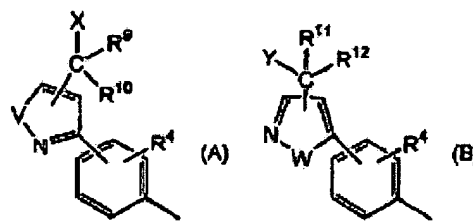
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At **Abstract**, page 50, lines 6 – 10, delete “ R^4 is the same as R^4 in the above formula (A), each of R^{11} and R^{12} which are independent of each other, is a hydrogen atom, an alkyl group, an aryl group or a halogen atom, Y is a halogen atom, and W is an oxygen atom or a sulfur atom,” and insert “V and W are each an oxygen atom or a sulfur atom, X and Y are each a halogen atom, and $R^1 - R^4$ and $R^9 - R^{12}$ are as defined in the Specification---”.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The present

invention is directed to 1,2-dioxetane derivatives of formula (I),  (I), where



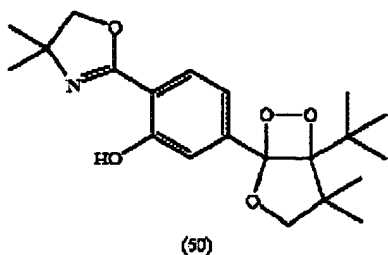
variable “Ar” is a group of formula (A) or formula (B):

where “V” and “W” are an oxygen atom or a sulfur atom (and other variables such as R^4 and $R^9 - R^{12}$ are as defined in the application), a chemiluminescent reagent containing the 1,2-dioxetane derivative of formula (I), and the claimed uses of the 1,2-dioxetane derivatives of formula (I), including a method to “have luminescence generated” and a method to measure hormones, alpha-fetoprotein (AFP), carcinoembryonic antigen (CEA), viral antigens and antibodies, and nucleic acids.

The compounds of the present invention were free of the prior art because of the 1,2-oxazole/1,2-thiazole group within substituent “Ar” (or by substituent “ R^4 ” within substituent “Ar”) attached directly to the 1,2-dioxetane group.

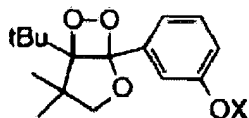
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The closest prior art of record for the **products** of the present invention was a 1,2-dioxetane derivative disclosed in U.S. Patent 6,218,135 (as appropriately cited by applicant on the Information Disclosure Statement), which disclosed the compound 5-*t*-butyl-1-(3-hydroxy-4-(4,4-dimethyl-4,5-dihydrooxazol-1-yl)phenyl)-4,4-dimethyl-2,6,7-trioxabicyclo[3.2.0]heptane,



(See U.S. Patent 6,218,135 at col. 50, lines 1 – 10, Example 8, “compound 60”). Although this compound would meet the limitations of the present invention as to **R¹**, **R²**, **R³**, and **R⁴**, it would not anticipate or render obvious the limitations as to substituent **Ar**, which require a 1,2-oxazole or 1,2-thiazole group attached to the phenylene ring that links it with the 1,2-dioxetane core, *two* double bonds in the five-membered ring, substitution by a methyl group having at least one halogen atom (**X** or **Y**), as well as bonding of the oxazole ring to the phenylene group via the 3- or 5-position carbon atom.

The closest prior art for **methods of using** 1,2-dioxetane derivatives to emit chemiluminescence was in a publication by Waldemar Adam, et al., in which 1,2-dioxetane

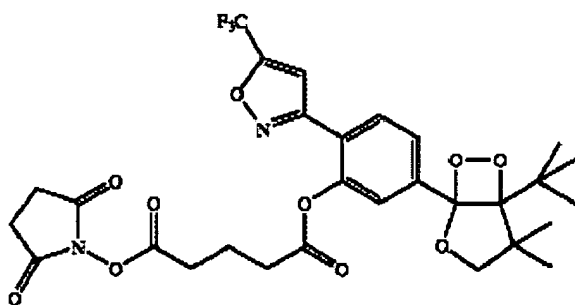


derivatives of formula **6a** (X=SiMe₂tBu) were shown to emit fluorescence in both protic and aprotic solvents by the decomposition of the 1,2-dioxetane structure. See Adam, W., et al., “Hydrogen-Bonding Effects on the Fluorescence versus Electron-Transfer-Initiated Chemiluminescence Spectra of the *m*-Oxybenzoate Ion Derived from a Bicyclic Dioxetane,” J.

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Org. Chem., vol. 65(7), pages 2078 – 2082 (Apr. 2000) at p. 2079, lines 1 – 3 (Scheme 2, compound 6a) and lines 12 – 32; see also Adam, W., et al., “Solvatochromic Effects on the Electron Exchange Chemiluminescence (CIEEL) of Spiroadamantyl-Substituted Dioxetanes and the Fluorescence of Relevant Oxyanions,” J. Phys. Chem. A, vol. 102(28), pages 5406 – 5414 (July 1998), at p. 5407, Scheme 1, “compound 1e.” [In this particular context, “fluorescence” as used in the prior art is the same phenomenon as “chemiluminescence” in the present invention]. In addition, Adam et al. also disclosed the “fluorescence quantum yield” (Φ^f) resulting from the decomposition of compound 6a in D₂O (a protic solvent) as 0.110, which would meet the additional limitation of **Claim 10** in the present invention if the starting material (i.e., the 1,2-dioxetane compound of formula (I)) had been the same. See Adam, et al., J. Org. Chem., *supra*, at p. 2080, Table 1.

Two co-pending applications, now **U.S. Patent No. 6,747,160** and **U.S. Patent No. 6,844,453**, which have all inventors and the same assignee in common with the present application, are distinguishable from the present invention even though both have similar claims and each discloses the chemical compound 5-(5-*t*-butyl-4,4-dimethyl-2,6,7-trioxabicyclo[3.2.0]hept-1-yl)-2-(5-trifluoromethylisooxazol-3-yl) phenylsuccinimidyl glutarate,



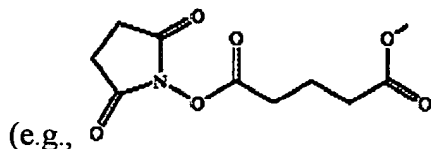
, which has the same “1,2-dioxetane-phenylene-isoxazole” skeleton as found in the present invention. See **U.S. Patent No. 6,747,160** at col. 34,

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lines 32 – 44 (Example 36) and U.S. Patent No. 6,844,453 at col. 35, lines 1 – 32 (Example 36).

However, the claims and the disclosed compound from U.S. Patent No. 6,747,160 and U.S.

Patent No. 6,844,453 differ from the present invention in the substituent at the “R⁴” position



render obvious the compounds (or methods of using those compounds) claimed in the present invention.

Therefore, based on the analysis above, **Claims 1 – 10**, as amended by the Examiner's Amendment authorized by applicant, are neither anticipated nor rendered obvious over the prior art of record, and are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

After examination of the elected invention, the Restriction requirement in the previous office action (Feb. 10, 2005, by examiner Sam Siefke) was withdrawn, and **Claims 5 – 10** were rejoined for examination on the merits.

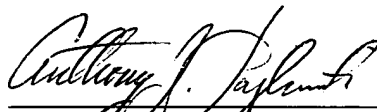
Claims 1 – 10, as amended by the Examiner's Amendment authorized by the applicant (above), are allowed.

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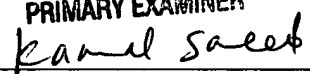
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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